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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,259	11/14/2003	Elaine Merisko-Liversidge	029318-0979	8061

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

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06/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,259	MERISKO-LIVERSIDGE, ELAINE	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,17,18 and 24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,17,18 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-13-07; 4-3-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment, RCE and response dated 4-3-07 is acknowledged.

Claims 1, 3-15, 17, 18 and 24-39 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 4-3-07 has been entered.

The following new rejection is applied to instant claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ

619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3-15, 17, 18 and 24-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,969,529. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims recite the same crystalline drug, particle sizes and surface stabilizer of the instant claims. Accordingly, the patented claims anticipate instant claims as well as the pharmacokinetic parameters such as the Tmax, AUC etc. For the claims reciting solid dosage form, while the patent claims do not recite a solid drug, instant claims do not recite any additional ingredients that differentiate form the composition of the patented claims. Further, different types of dosage forms i.e., solid, liquid, aerosols etc., are conventional in the art of pharmacology and accordingly preparing a solid or a liquid dosage form would have been within the scope of a skilled artisan.

2. Claims 1, 3-15, 17, 18 and 24-39 are directed to an invention not patentably distinct from claims 1-38 of commonly assigned patent US 6,969,529.

Specifically, the claimed nifedipine compositions of the instant claims are also claimed in the above patent.

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,969,529, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3-15 and 29-39 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,969,529 to Bosch et al ('529).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

'529 teach nanoparticulate compositions comprising nifedipine and a surface stabilizer (example 2). '529 teach the same particle size ranges (col. 4, L 46-64), and surface stabilizers as that claimed in the instant application (col. 3-4). In particular, example 2 recites vinyl pyrrolidone and vinyl acetate copolymer. For the amounts of drugs and surface stabilizer, see col. 4, L 66-15). The method of

preparing the nanoparticle described in '529 is identical to the instant disclosed method. Claims 29-39 are dependent upon claim 1, which recites only nifedipine and a surface stabilizer. '529 also exemplify the claimed ingredients and accordingly, the claimed Tmax, AUC and the bioequivalence of claims 29-39 are inherent to the composition of '529.

4. Claims 1, 3-8, 10-12, 14 and 29-39 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kim et al (Br. J. Pharmacology, 1997).

Kim teaches orally administered nifedipine particles treated with Pluronic F68 (which is also known as poloxamer, recited in claim 11), which is a non-ionic surfactant and hence meets the instant surface stabilizer limitation of claim 1, 10 and 12. Kim teaches nifedipine in the nanoparticle size range of 211, 118 or 172 nm (table 1, page 401), which meets the instant claimed particle size ranges. Kim teaches the plasma concentrations of nifedipine in terms of Cmax, released from nifedipine nanoparticles treated with Pluronic as opposed to those from conventionally loaded in to polyethylene glycol (rapid release) (see columns bridging pages 399-400). Kim states that the nifedipine compositions provide a controlled release of the drug and increased bioavailability when loaded with Pluronic and the biodegradable polymers than with nifedipine dissolved in PEG (see the results discussed on pages 401, 402 and the paragraph bridging the two columns on page 403). Instant claims 29-39 do not recite any additional components other than nifedipine and the surface stabilizer, both of which are

also taught by Kim. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Further, in view of the controlled release characteristics taught by Kim, it is examiners' position that the claimed Tmax, and AUC are inherent to the composition of Kim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al in view of US 4,814,175 or US 6,969,529 ('529) in view of US 4,814,175.

Kim et al as well as '529 fail to teach a combination of the active agents and the redispersibility. While '529 suggests different solid dosage forms, Kim does not explicitly teach a solid form and instead teaches administering oral compositions as mg/ kg, which indicates that the compositions are solid. .

175 teach a combination of particulate nifedipine and a beta-blocker for treating cardiovascular diseases, and states that a combination allows for a reduced dose of nifedipine and affords an advantage over a conventional

preparation i.e., provides a prolonged therapy for a 24-hour period. '175 also teach preparing solid dosage forms such as tablets or capsules.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to combine nifedipine of Kim or '5299 with other therapeutic compounds such as beta blockers and also prepare the nanoparticulate nifedipine of Kim or '529 as tablets or capsules (solid) because '175 suggests a combination therapy of nifedipine and beta blocker and one of an ordinary skill in the art would have expected to treat cardiovascular diseases with a lower amount of nifedipine and for a prolonged period. For claims 24-28, while Kim or '529 do not mention redispersibility, both the compositions exhibit the property because according to the instant specification, the nanoparticle nifedipine exhibits redispersion upon administration at a biorelevant pH, which is stomach pH ([0066 and 0067]). Claims 24-28 depend from claim 1, which recites nothing more than nanoparticulate nifedipine and a surface stabilizer, both of which are taught by Kim et al and '529.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-15, 17, 18 and 24-39 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone

number is 571-272-0591. The examiner can normally be reached on 7.00 AM - 4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
June 21, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER